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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/663,684 | 09/17/2003 | Steven C. Walker | ISR00-10 19 | 2451 |

27370 7590 10/03/2005

OFFICE OF THE STAFF JUDGE ADVOCATE
U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
ATTN: MCMR-JA (MS. ELIZABETH ARWINE)
504 SCOTT STREET
FORT DETRICK, MD 21702-5012

EXAMINER

NATARAJAN, VIVEK

ART UNIT PAPER NUMBER

3736

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/663,684

Applicant(s)

WALKER ET AL.

Examiner

Vivek Natarajan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 4, 5, 23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-22 and 25-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/9/04, 3/8/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species of the claimed invention:

A monitoring device comprising a needle assembly with a:

- A. Straight needle body with a linear arrangement of ports (Fig.2)
- B. Straight needle body with a serpentine arrangement of ports (Fig.3)
- C. Straight needle body with a circumferential arrangement of ports (Fig.4)
- D. Arcuate needle body (Fig.6)
- E. Two-pronged needle body (Fig.7)

2. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-3, 7-22 and 25-26 are generic.

3. During a telephone conversation with Mr. George Metzenthin on 9/26/05 a provisional election was made without traverse to prosecute the invention of Species B, Claim 6. Affirmation of this election must be made by applicant in replying to this Office action. Claims 4-5 and 23-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

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is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

5. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Specification

7. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The

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abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

8. The abstract of the disclosure is objected to because it includes improper language such as "this invention relates", "according to the invention", and the term "preferably". Correction is required. See MPEP § 608.01(b).

Claim Objections

9. Claim 2 is objected to because of the following informalities: Applicant should use consistent terminology when referring to a particular element. In Claim 1 the phrase "a pointed tip end" is defined and then is referred to as "said tip", while Claim 2 uses the phrase "said pointed tip end". Appropriate correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 2-3 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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12. Applicant recites in Claim 2 that "said ports comprise a central port defined by said pointed tip", but indicates in Claim 1 that the plurality of ports are defined by the sidewall and not the tip. It is not possible for both of these limitations to be met simultaneously, and consequently Claim 2 is unclear.

13. Claim 3 recites the limitation "said side ports", but Claim 2 indicates that there need only be at least *one* side port. Therefore, there is insufficient antecedent basis for this limitation in Claim 3.

14. Claim 9 recites the limitation "said sensor". There is insufficient antecedent basis for this limitation in the claim. It appears that the claim should depend from Claim 8 rather than Claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

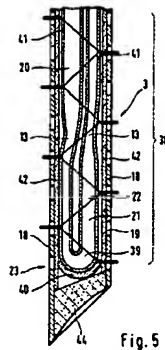
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Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

16. Claims 1-3, 6-9, 12-14, 16-19, 22 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Haar et al. (US Patent No. 6,584,335).

17. Haar discloses a monitoring device comprising a needle assembly having a needle body 18 with an open back end and a pointed tip end 23 adapted to pierce human tissue. The needle body includes a central port 24 and a sidewall defining a long-narrow lumen extending between said open back and said tip, with said sidewall further including a plurality of side ports 19 disposed in a pattern on the needle body between the tip and back end. The needle body also includes fiber optic tracks 20, 21, 25, 26 in communication with said ports. The monitoring device comprises an LED radiation source 9 in communication with the fiber optic track 20, 25 and a photodetector 27 in communication with the fiber optic track 21, 26. The monitoring device further includes a spectrophotometer sensor 6 for receiving and interpreting information communicated from said photodetector (see Figs.3 and 5 and the description thereof in col.6, line 63 – col.8, line 5 and col.9, lines 16-42).

18. Regarding Claim 6, the side ports 19 are disposed in a serpentine configuration around a length of the needle body. The following image illustrates this configuration:



Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claims 15 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haar et al. as applied to Claims 1, 14 and 16 above, and further in view of Schwartz (US Patent No. 6,746,404). Haar discloses the claimed fiberoptic needle as described in ¶17 above but does not include a barb means for anchoring the needle in the specimen to be monitored. Schwartz teaches that tissue-piercing barbs may be utilized to anchor a medical device within human tissue (see Fig.4 and the description thereof in col.9, lines 25-31). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the fiberoptic needle as disclosed by Haar to include tissue-piercing barbs as taught by Schwartz since this allows the device to be anchored firmly within the tissue.

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21. Claims 10-11 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haar et al. as applied to Claims 1, 7-9 and 25 above, in view of Bornstein et al. (US Patent No. 5,436,454) and further in view of Jobsis (US Patent No. 4,281,645). Haar discloses the claimed fiberoptic needle utilizing infrared spectrophotometry for detecting an analyte in vivo, but uses this needle to analyze interstitial fluid rather than blood and does not expressly disclose the particular analyte to be detected. Bornstein discloses a similar fiberoptic needle introduced through the skin of a patient into a blood vessel to enable infrared spectrometry of blood in vivo. Jobsis teaches that hemoglobin possesses absorption characteristics within the infrared region of the spectrum that permit detection of the Hb-HbO₂ steady-state and consequently allow continuous monitoring of oxygen saturation (col.5, line 33 – col.6, line 13). It would have been obvious to one having ordinary skill in the art at the time the invention was made to adapt the fiberoptic needle device as disclosed by Haar to be insertable into a blood vessel as disclosed by Bornstein and to transmit particular wavelengths characteristic of the absorbance spectrum of oxyhemoglobin and deoxyhemoglobin as taught by Jobsis, since this allows blood oxygen saturation to be effectively measured.

22. Claims 1, 7-9 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Combs et al. (US Patent No. 6,280,703), in view of Haar et al. and further in view of Bornstein et al. Combs teaches that the blood clearance of indocyanine green and other tracers can be measured by administering the tracer into the body and utilizing an invasive light-scattering technique well known in the art to detect the presence of the

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tracer, but does not disclose a specific structure for invasive detection of the tracer (col.5, lines 3-50). Haar in view of Bornstein teaches that a fiberoptic needle with an open back end, pointed tip end, sidewall defining a lumen and a plurality of ports, a radiation source, light detector, and spectrophotometric sensor can be introduced through the skin of a patient into a blood vessel and utilize infrared spectrophotometry to detect levels of a blood analyte. It would have been obvious to one having ordinary skill in the art at the time the invention was made to implement Combs' method of invasively detecting indocyanine green clearance in conjunction with the fiberoptic needle as disclosed by Haar in view of Bornstein since this allows hepatic function to be quantitatively measured.

Conclusion

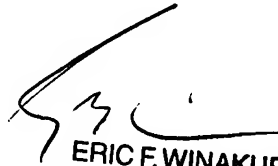
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vivek Natarajan whose telephone number is (571)272-6249. The examiner can normally be reached on Mon-Fri, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571)272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VN



ERIC F. WINAKUR
PRIMARY EXAMINER